



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

DP BARCODE No.: D451289; FILE SYMBOL/REG. No.: 91960-1; PRODUCT NAME: Bifenthrin
Technical; DECISION No.: 548608; PC Code(s): 128825; ACTION CODE: R351x2; FOOD Use: Yes

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DATE: November 21, 2019

SUBJECT: Product Chemistry Review of "Bifenthrin Technical"

FROM: Dehui Duan, Chemist
Product Chemistry Team
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

TO: Vanessa Emerson / Catherine Aubee, RM 03
IVB1 / RD (7505P)

REGISTRANT: GENSOURCE INC.

MRID Number(s): 50779701-50779704

INTRODUCTION:

The registrant is seeking to add two new sources of Bifenthrin Technical. The registrant has submitted two proposed alternate CSFs #2 and #4, both dated 02/09/2019, Group A and Group B chemistry data with MRID Nos. 50779701-50779704. Per Agency's advice, the registrant submitted a revised alternate CSF #4 dated 02/09/2019 to change the certified limits of impurities.

The approved basic CSF dated 02/03/2016 – Nominal concentration: 98.5% - [REDACTED]

The proposed Alternate CSF #2 dated 02/09/2019 – Nominal concentration: 98.37% - [REDACTED]
[REDACTED] – MRID#: 50779703 and 50779704.

The proposed Alternate CSF #4 dated 02/09/2019 – Nominal concentration: 98.50% - [REDACTED]
[REDACTED] – MRID#: 50779701 and 50779702.

CITAB has been asked to determine the acceptability of the product chemistry data and two proposed alternate CSFs.

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550: (product identity & composition)

The active ingredient on the proposed Alternate CSF #2 was adequately described (MRID 50779703).
The nominal concentration of the active ingredient (98.37%) is the same as the average derived from the

Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: D451289; **FILE SYMBOL/REG. No.:** 91960-1; **PRODUCT NAME:** Bifenthrin
Technical; **DECISION No.:** 548608; **PC Code(s):** 128825; **ACTION CODE:** R351x2; **FOOD Use:** Yes

five-batch preliminary analysis results (98.365 %, from Page 13 of 365 in the Confidential Attachment of MRID 50779704). It is comparable to that stated on the approved basic CSF (98.37 vs 98.5%).

The active ingredient on the proposed Alternate CSF #4 was adequately described (MRID 50779701). The nominal concentration of the active ingredient (98.5%) is the same as the average derived from the five-batch preliminary analysis results (98.5 %, from Page 355 of 614 in the Confidential Attachment of MRID 50779702). It is also the same as that stated on the approved basic CSF.

The information presented meets the data requirements for 40 CFR 158.320.

830.1600: (description of materials used to produce the product)

Safety Data Sheets (SDSs) of all the starting materials, and their specifications and suppliers were provided respectively in the MRID Nos. 50779701 and 50779703. The information presented meets the data requirements for 40 CFR 158.325.

830.1620 (description of production process)

A detailed description of the production process, vessels and equipment, in process control measures, flow charts and recycling procedure were included respectively in MRID Nos. 50779701 and 50779703. The information presented meets the data requirements for 40 CFR 158.330.

830.1670 (discussion on the formation of impurities)

Potential impurities listed on the alternate CSF #2 were identified and quantified as part of the five-batch analysis (MRID 50779704). [REDACTED] impurities were detected at levels greater than 0.1%. The formation and identities of the impurities were fully discussed in MRID 50779703.

Potential impurities listed on the alternate CSF #4 were identified and quantified as part of the five-batch analysis (MRID 50779702). [REDACTED] impurities were detected at levels greater than 0.1%. The formation and identities of the impurities were fully discussed in MRID 50779701.

The information presented meets the data requirements for 40 CFR 158.335.

830.1700 (preliminary analysis)

[REDACTED]

The active ingredient and its associated impurities in the five batches represented by the alternate CSF #4 were characterized and analyzed in similar ways as described above.

The information presented meets the data requirements for 40 CFR 158.345.

830.1750 (certified limits)

The proposed upper and lower certified limits for the active ingredient on both proposed alt CSFs (dated 2/9/2019) are within the range of the guideline OCSP 830.1750 recommendation. The upper and lower

DP BARCODE No.: D451289; **FILE SYMBOL/REG. No.:** 91960-1; **PRODUCT NAME:** Bifenthrin Technical; **DECISION No.:** 548608; **PC Code(s):** 128825; **ACTION CODE:** R351x2; **FOOD Use:** Yes

certified limits of A.I. isomer and the upper limits of all impurities were proposed based on the results of five-batch analysis. The information presented meets the data requirements for 40 CFR 158.350

830.1800 (enforcement analytical method)

The analytical method for quantifying the active ingredient in Bifenthrin Technical was HPLC with external standard calibration, which was validated for specificity, linearity, accuracy and precision (MRID 50779702 and 50779704).

The methods for quantifying impurities listed on alternate CSF #2 were validated in terms of specificity, selectivity, linearity, precision, intermediate precision, accuracy, LOQ and LOD (MRID 50779704).

The methods for quantifying impurities listed on alternate CSF #4 were validated in terms of specificity, selectivity, linearity, system precision, method precision, accuracy and precision (MRID 50779702).

All methods are capable of determining whether an ingredient falls within its certified limits. The information presented meets the data requirements for 40 CFR 158.355.

2. Group B guidelines (physical-chemical properties):

| Guideline No. | Study Title | Value or Qualitative Description | CITAB's Assessment of Data | MRID Nos. |
|----------------------|--------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|------------------|
| 830.6303 | Physical State | Granular solid with mild acidic odor | A | 50779702 |
| 830.6314 | Oxidation/reduction | Compatible with common oxidizing and reducing agents. | A | 50779702 |
| 830.6315 | Flammability | Not applicable. | A | Data Matrix |
| 830.6316 | Explosibility | Not applicable. | A | Data Matrix |
| 830.7000 | pH | 5.6 (1% w/v) at 20 °C | A | 50779702 |
| 830.7100 | Viscosity | Solid. Not required. | A | Data Matrix |
| 830.7300 | Density (units) | 1.2549 g/mL @ 20 °C | A | 50779702 |
| 830.6317 | Storage stability Or Accelerated storage stability | Product is stable when stored at 54 °C for 14 days. | A | 50779702 |
| 830.6320 | Corrosion characteristics or Accelerated corrosion characteristics | No significant corrosion was observed on the aluminium, polyethylene (HDPE) or mild steel with PVF lining discs when in contact with Bifenthrin TGA1 under the test conditions | A | 50779702 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable; I = In progress

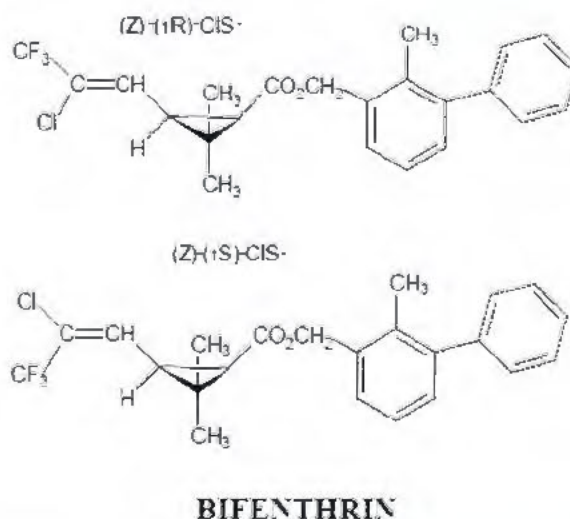
CONCLUSIONS:

The CITAB has reviewed the proposed alternate CSFs #2 and #4 (dated 02/09/2019) and the supporting Group A and Group B data for Bifenthrin Technical and has concluded that:

1. The product chemistry Group A data submitted for guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
2. No impurities of toxicological concern with nominal concentration greater than 0.1% w/w were found in the two new formulations.
3. The product chemistry Group B data are acceptable.
4. The proposed alternate CSF #2 (dated 02/09/2019) is acceptable.
5. The proposed alternate CSF #4 (dated 02/09/2019) is acceptable. There is a typo in Box A of Page 2. It should be changed to formulation #4.

Active Ingredient

mites. Bifenthrin is the accepted common chemical name for the active ingredient (2-methyl [1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylate. The empirical formula for Bifenthrin is $C_{23}H_{23}ClF_3O_2$, it is also identified by CAS Registry Number 82657-04-3, and EPA Chemical Code 128825. The structural formula for Bifenthrin is:



| Component of Bifenthrin TGA1 | Analytical Method Used | Linearity of Response (Correlation Coefficient) | System Precision (%) | Method Precision (%) | Assay Accuracy (%) | Assay Precision (%) | Validation Level (% w/w) |
|------------------------------|------------------------|-------------------------------------------------|----------------------|----------------------|--------------------|---------------------|--------------------------|
| Active Ingredient | AN17042601-A | 1.0000 | 0.1 | 0.1 | 100.1 | 0.3 | 80-120 |

Table 6 Five Batch Analysis: Active Ingredient Content (Analytical Method No. AN17042601-A)

| Bifenthrin TGA1 Batch Number | Determined Concentration (% w/w) | Mean Determined Concentration (% w/w) | Coefficient of Variation (%) | QC Recoveries (%) |
|------------------------------|----------------------------------|---------------------------------------|------------------------------|-------------------|
| H201706017 | 98.0 98.0 98.2 | 98.1 | 0.1 | 100.0 |
| H201706018 | 98.5 98.5 99.0 | 98.8 | 0.3 | 99.9 |
| H201706019 | 98.6 98.3 98.7 | 98.5 | 0.2 | 100.1 |
| H201706020 | 98.9 98.6 98.9 | 98.8 | 0.2 | 100.0 |
| H201706021 | 98.5 98.3 98.6 | 98.5 | 0.2 | 100.1 |

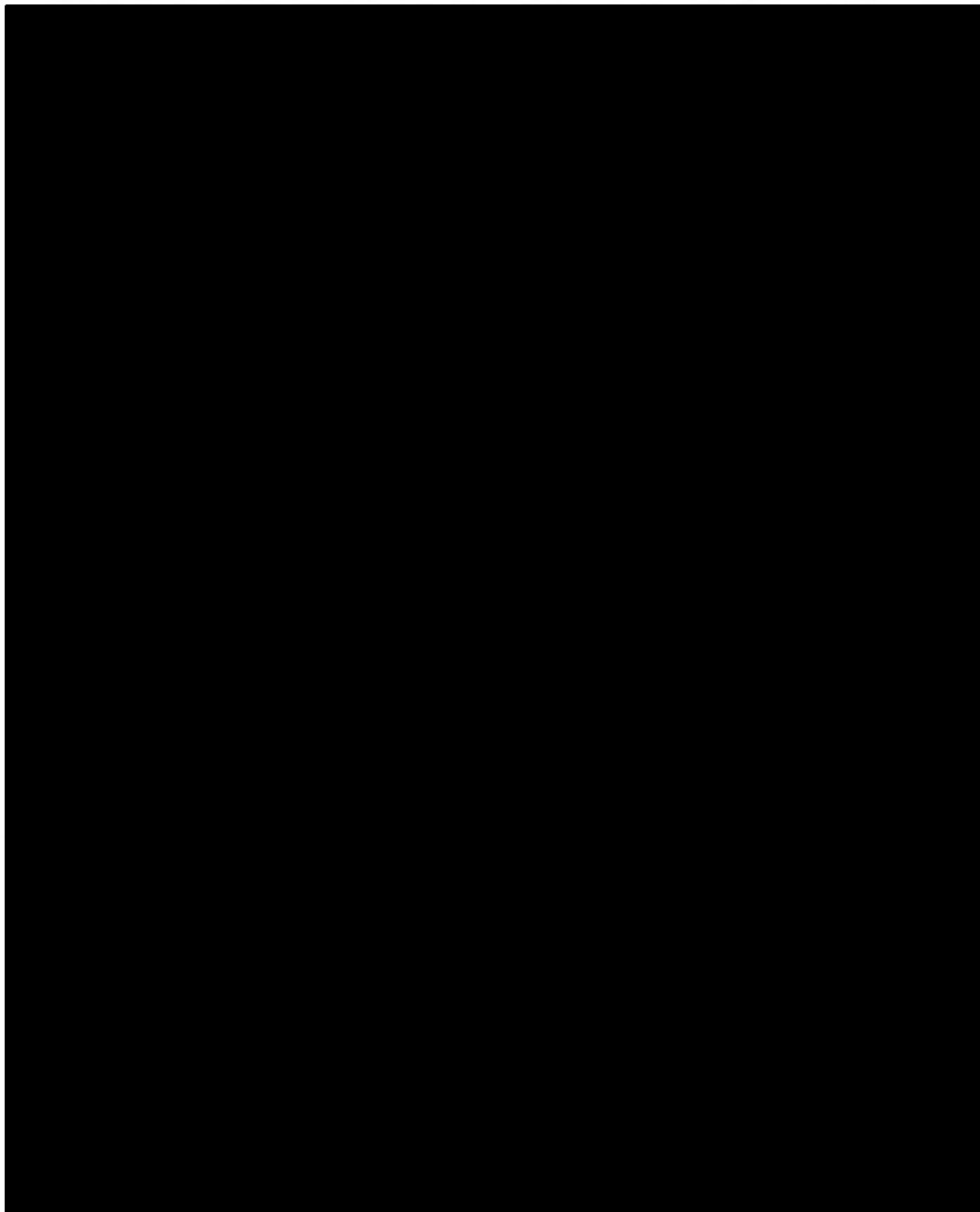
Mean Determined Concentration (5 batches) = 98.5% w/w
 Standard Deviation ($\sigma_{\text{D.C.}}$) = 0.29

Mean QC Recoveries = 100.0%. Coefficient of Variation = 0.08%

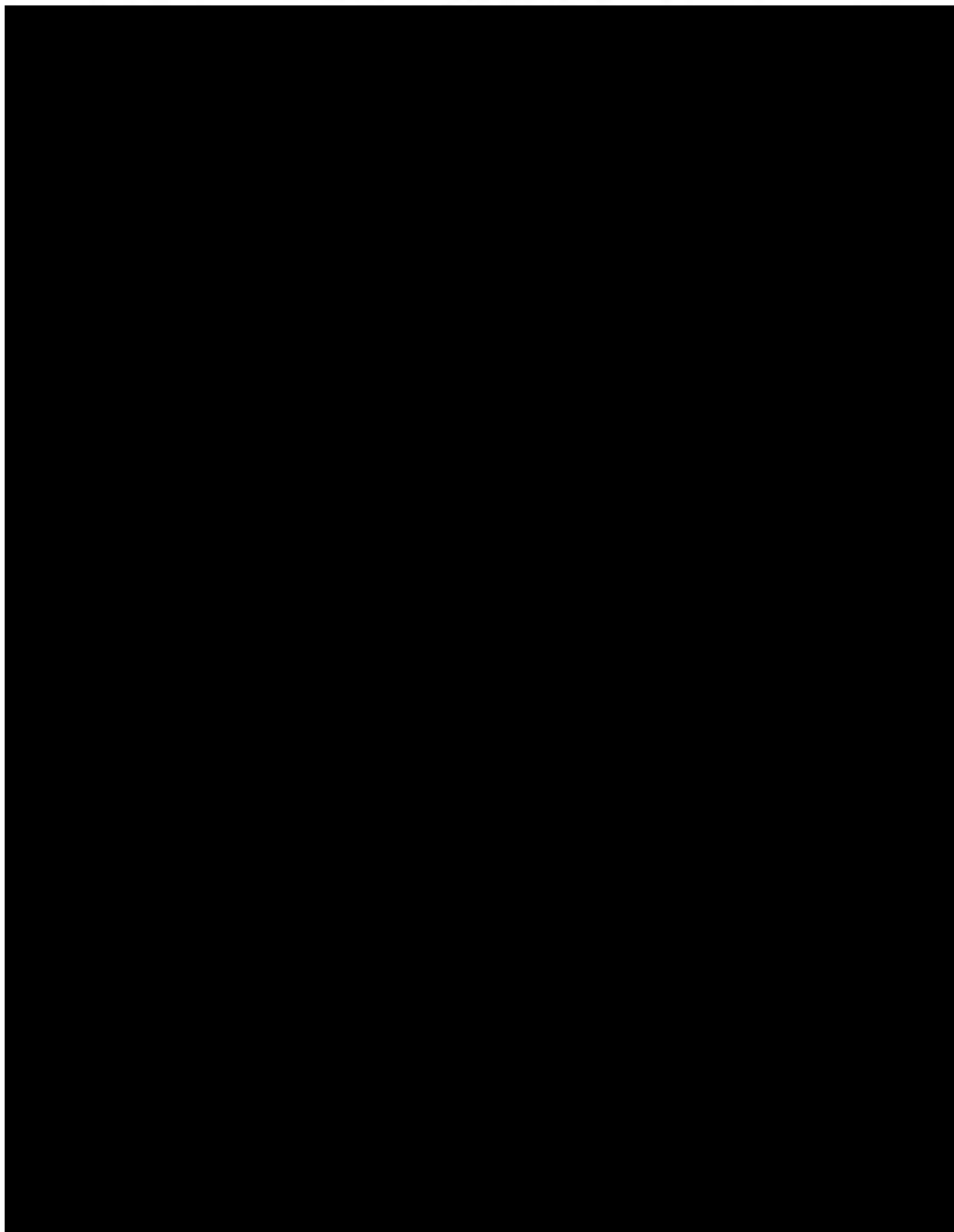
Confidential Appendix



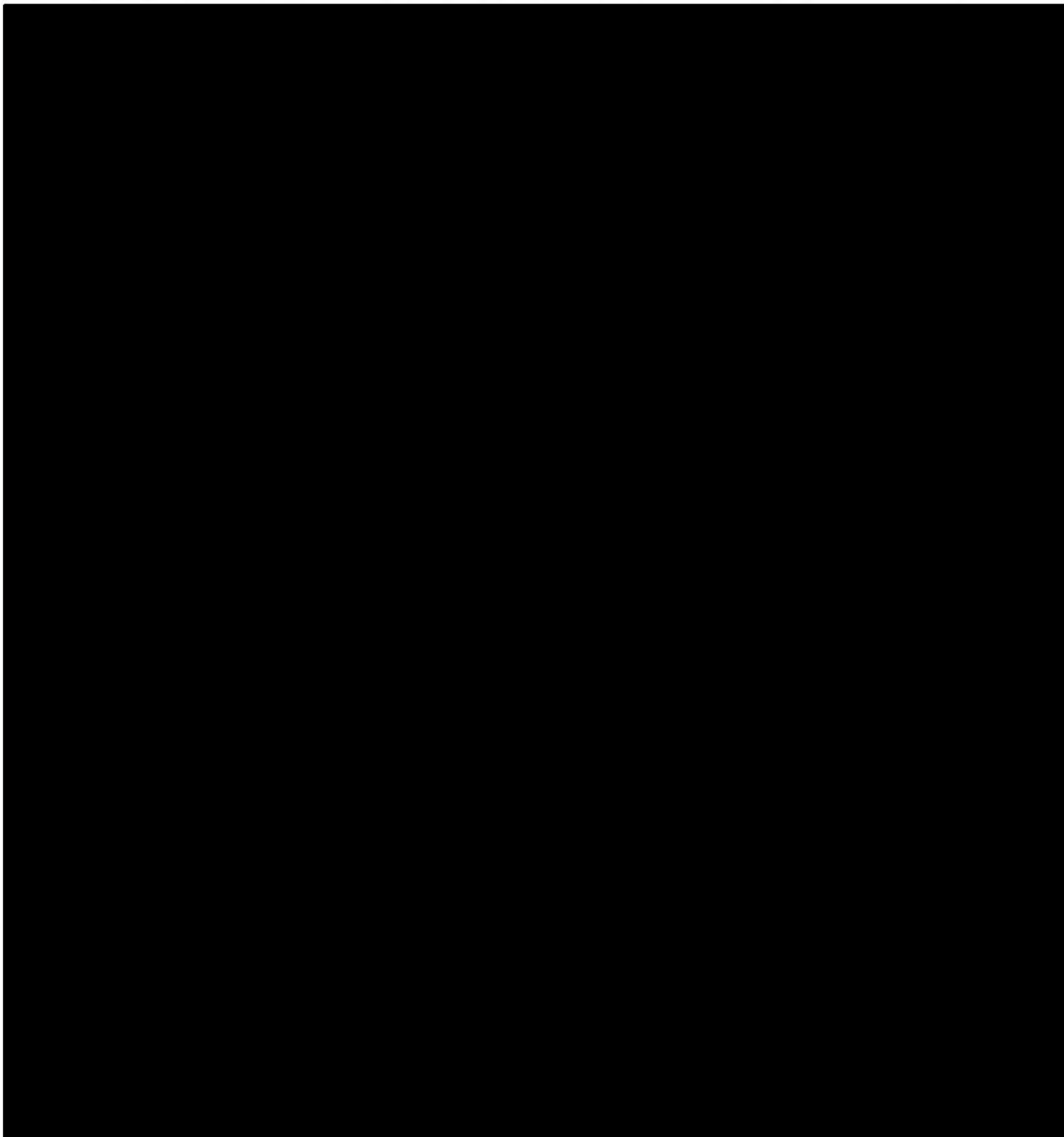
Manufacturing process information may be entitled to confidential treatment



Manufacturing process information may be entitled to confidential treatment



Manufacturing process information may be entitled to confidential treatment



Manufacturing process information may be entitled to confidential treatment

